REMARKS

Claims 1-29 are pending in the subject application. Applicant has amended claims 1, 19, 27, and 28 and has cancelled claims 5, 14-18, 22 and 26. Accordingly, upon entry of this amendment, claims 1-4, 6-13, 19-21, 23-25 and 27-29 will be pending.

Support for the amendment to claim 1 may be found, *inter alia*, at page 9, lines 5-7; page 15, lines 29-32 of the subject application; and the paragraph spanning pages 664-665 of Vollmer et al., *Multiple Sclerosis* 2008; 14: 663-670.

Claims 19, 27 and 28 have been amended to correct claim dependencies in view of the cancellation of claims 18 and 26.

Examiner's Comments

In the February 18, 2010 Advisory Action, the Examiner asserted that under the broadest reasonable interpretation of the claims the invention as claimed is drawn to administering mitoxantrone and then glatiramer acetate periodically as recited in original claim 1 rather than a combination.

Applicant's response

In response, without conceding the correctness of the Examiner's assertions and for the purpose of expediting prosecution, applicant has amended claim 1 to recite administration which provided enhanced efficacy as shown by Vollmer et al. (previously submitted with applicant's August 3, 2009 Amendment in response). Applicant points to page 9, lines 5-7 of the subject application which clearly recites that the administration of the mitoxantrone substantially precedes the administration of the glatiramer acetate. In addition, applicant points to page 15, lines 29-32 of Example 1 which discloses the details of the treatment regimen i.e., IV infusion of mitoxantrone at Months 0, 1 and 2 followed by

daily subcutaneous injections of glatiramer acetate two weeks after the last scheduled infusion of mitoxantrone. The results of applicant's disclosed treatment regimen are described in Vollmer et al., *Multiple Sclerosis* 2008; 14: 663-670, *inter alia*, in the paragraph spanning pages 664-665.

The subject application clearly discloses at page 21, lines 7-12 that

> *In comparison to the group receiving Copaxone® alone, the group receiving Novantrone® followed by Copaxone® exhibited comparable or greater performance on the primary and secondary safety measures. The administration of Novantrone® followed by Copaxone® results in comparable or greater results in the secondary efficacy outcome measures.* (emphasis added)

Applicant points out that safety and efficacy of the claimed treatment are diclsoed at page 17, lines 18 to 27 and page 17, line 29 to page 18, line 6 of the subject application.

Moreover, applicant's prophetic examples are validated by applicant's published results wherein applicant has made the unexpected observation that immunosuppression with mitoxantrone accelerates and enhances the efficacy of glatiramer acetate administered to the patient (see, e.g. page 15, lines 15-18 of the subject application; and abstract of Vollmer et al., *Multiple Sclerosis* 2008; 14: 663-670). Specifically,

- applicants observed that mitoxantrone-glatiramer acetate induction produced an 89% greater reduction in the number of Gd-enhancing lesions at months 6 and 9 and 70% reduction at months 12 and 15 versus glatiramer acetate alone;
- mean relapse rates were 0.16 and 0.32 in the mitoxantrone-glatiramer acetate and glatiramer acetate groups, respectively; and

- short-term immunosuppression with mitoxantrone followed by daily GA for up to 15 months was found to be safe and effective, with an early and sustained decrease in MRI disease activity.

Applicant's amended claims are commensurate in scope with these results. Accordingly, applicant requests that the Examiner reconsider and withdraw the rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed $810.00 fee for filing of an RCE and $1,110.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Gary J. Gershik

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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